

*9/ Prior
Art 4/alt*

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Yoshihisa NISHIBE, et al.

Appln. No. 09/446,276

Group Art Unit: 1615

Confirmation No.: Unknown

Examiner: A. PULLIAM

Filed: December 21, 1999



For: PHARMACEUTICAL COMPOSITION FOR APPLICATION TO MUCOSA

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached Form PTO-1449 and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith.


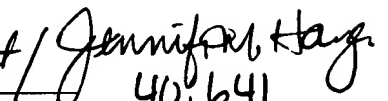
The present Information Disclosure Statement is being filed after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application.

Complete English translations of foreign language documents are being submitted herewith, and therefore no concise explanation for such foreign language documents is required.

INFORMATION DISCLOSURE STATEMENT
U.S. Appln. No. 09/446,276

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Respectfully submitted,

 / 
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(ENGLISH TRANSLATION)

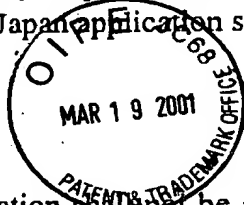
FIRST OFFICE ACTION

Ref. : Chichuan No.09083001789

Date of Receipt : February 5, 2001

1. APPLICATION NO. : 88106305
TITLE : PHARMACEUTICAL COMPOSITION FOR APPLICATION TO MUCOSA
2. APPLICANT : TEIJIN LIMITED
ADDRESS : JAPAN
4. ATTORNEY : PATRICK I.C. YUN AND WILLIAM W.L. CHEN
5. FILING DATE : April 20, 1999
6. PRIORITY: Japan application serial nos. 110887 and 110888 both filed 1998/04/21
7. CONTENTS

SUBJECT :



This application shall not be granted an Invention Patent on the basis of Articles 20.1 (first paragraph), 20.2, 22.3 and 22.4 of the Patent Law.

REASONS :

- (1). The invention in this application entitled, "Pharmaceutical Composition for Application to Mucosa," relates to a pharmaceutical composition for application to the mucosa comprising a water-insoluble and /or water-low soluble substance, an aqueous medium and a pharmacologically active compound, and having an osmotic pressure of less than 290 mOsm. However, it was disclosed in the prior art that not all pharmacologically active compounds have the effect of application to the mucosa (see attachments 1 to 27). Moreover, only a few examples of the claimed pharmaceutical compositions have the effect of the application to the mucosa (such as bioavailability). Therefore, this invention can be easily achieved by a person skilled in the art and does not meet the patent requirements.
- (2). As can be appreciated from the given examples of this invention, the application to the mucosa under an osmotic pressure of less than 290 mOsm cannot always increase the effect of the application to the mucosa (such as bioavailability). Therefore, this invention does not meet the patent requirements.
- (3). In view of the above reasons, the pharmaceutical composition for application to the mucosa as claimed in the amended claims 1 to 3 submitted on June 21, 2000 does not meet the patent requirements.

In view of the aforesaid, this invention shall not be granted an Invention Patent as it contravenes the provisions in Articles 20.1 (first paragraph), 20.2, 22.3 and 22.4 of the Patent Law.

Sealed by

Ming-Pang Chen
Director

Not : If dissatisfied with this Office Action, the Applicant may file a request for re-examination within 30 days of the day following the date of receipt of this Office Action.